## REMARKS

### I. Introduction

This paper is filed in response to the Final Action mailed August 11, 2004 in the above-referenced application. In this Response, there are no claim amendments. Claims 1, 2, 30, 43-45, 58-64, 73 and 82-87 are currently pending and of these claims, claims 1 and 58 are independent. No new issues are raised. No new search is required. And the claims are in condition for allowance. Entry of this Response is merited.

In an in-person interview with the Examiner that occurred on February 19, 2004, the Examiner agreed that certain proposed claim amendments would overcome the asserted prior art rejection.[1] There was no indication at the interview of any other issues associated with the claims (with the exception of a prior art update search). Those proposed claim amendments were then formally presented to the Examiner in an Amendment filed April 12, 2004.

Consistent with the agreement reached at the interview, the Examiner has declined to assert the prior art rejection in the final Office Action dated August 11, 2004 (and no additional prior art rejection has been made based on the updated search). However, the Examiner now raises a new rejection, this time based on the written description requirement of 35 U.S.C. Section 112, first paragraph.

This new rejection is particularly disappointing since the subject matter added to the claims in conformance with the agreement reached at the interview on February 19, 2004 simply clarifies what has long been recited and argued in this application for the last two years and never with any "Section 112" issues raised by the Examiner. The inventors are at a loss to understand this rejection given the lengths the inventors have gone to meet with the Examiner and respond to all issues in a timely fashion.

[1] The interview on February 19, 2004 was the second of two in-person interviews that have occurred in this application, the first occurring on September 24, 2002. Each interview involved the identical prior art rejection. And each interview resulted in agreement that the prior art rejection was overcome by certain proposed claims only to be followed by yet another rejection in a subsequent office action.

In hopes that the Examiner will finally concede the clear allowability of the pending claims so that a lengthy appeal process may be avoided, the Applicants hereby respond to the rejection as set forth below.

II. **Rejection Under 35 U.S.C. Section 112**

Claims 1, 2, 30 , 43-45, 58-64, 73 and 82-87 have been rejected under 35 U.S.C. Section 112 on grounds that they do not conform with the written description requirement. In particular, the Examiner asserts that "the original disclosure lacks any description of an embodiment which is substantially free of the holes larger than the microholes".

In response to this rejection, the Examiner is first directed to page 18, lines 1-4 of the originally filed application, where it is stated:

> Stent 14 is preferably a balloon expandable device made of expandable metal or braided wire, but also may be designed as a self-expanding structure. *It may also be fabricated from a composition of metallic fibers, **uniformly** laid to form a three dimensional, non-woven structure, such as is shown in Figure 2.* (emphasis added).

The Examiner is further directed to page 15, lines 8-15 of the originally filed application, where it is stated:

> Preferred metal stents are formed of a material comprising metallic fibers ***uniformly** laid to form a three-dimensional non-woven matrix and sintered to form a labyrinth structure exhibiting high porosity, typically in a range from about 50 percent to about 85 percent, preferably at least about 70 percent*. The metal fibers typically have a diameter in the range from about 1 micron to 25 microns. The average effective pore size is *in the stent body* such that cellular ingrowth into the pores and interstices is enhanced, for example having an average diameter in the range from about 30 microns to about 65 microns. (emphasis added).

These two citations (which include both text AND and a drawing figure) demonstrate that the application as originally filed clearly contemplated an embodiment supportive of the claims as currently pending. The citations show a stent of ***uniformly***

laid metallic fibers that create tiny pores and interstices ***in the stent body***. This can mean nothing other than an embodiment of "a stent having a plurality of interconnected microholes distributed throughout said stent body substantially uniformally along the entire length of said stent body, said plurality of microholes being sufficiently small so as to promote an organized growth pattern of infiltrating cells throughout said stent body." (claims 1 and 58). And most importantly, these citations clearly mean a stent body that is "otherwise substantially free of holes larger than said microholes."[2]

Yet these two citations are not the sole support found in the originally filed application. Further support is present at page 6, lines 7-10 and page 15, line19 through page 16, line 4 which also describe an embodiment of the claimed stent. The only difference is that, unlike the citations above, this embodiment involves a ***stent body*** made from a porous polymer as opposed to ***stent body*** made from a matrix of metallic fibers. But this distinction is immaterial as to the issue at hand since the basic configuration of the stent is the same in each embodiment and the claims are generic to both embodiments in any event.

In view of the foregoing, the rejection of the claims based on 35 U.S.C. Section 112, first paragraph is incorrect. Accordingly, the rejection should be withdrawn and the allowability of the claims indicated.

## III. Response to Other Comments by Examiner

### A. *"Support" Citations*

The Examiner has asserted that the Applicant failed to specifically point out the support in the original disclosure for each of the newly presented claim limitations, citing MPEP 714.02. First, it is submitted that the Examiner is simply incorrect.

The Amendment filed April 11, 2004, introduced new claims 83 and 86 each of which included the new recitation at issue in the current Section 112 rejection (by virtue of their dependency to claims 1 and 58, respectively). In doing so, the Applicants specifically directed the Examiner to page 15, line 9 of the original application as

[2] Indeed, the only reason that the "otherwise substantially free of holes larger than said microholes" phrase was added was to clarify (at the Examiner's request) that the microholes were "distributed throughout said stent body substantially uniformally along the entire length of said stent body."

providing the requisite support for the claimed invention. This citation is the very same citation discussed above that clearly shows support for the claimed invention, including the recitation now at issue.

Second, it is noted that the recitation at issue in the current rejection is a recitation that was added at the suggestion of the Examiner in the interview on February 19, 2004 to clarify ***existing*** claim language. Moreover, at no time was the existing claim language ever previously questioned (either formally in an office action or informally in an interview) under 35 U.S.C. Section 112.

B. *New Matter under M.P.E.P. 2163.06*

The Examiner seems to intimate that a prior art rejection may yet be applicable in light of the provisions of MPEP 2163.06. However, this portion of the MPEP pertains to new matter and no new matter has been added either in this response or at any time previous to this Response. Hence, M.P.E.P. Section 2163.06 should not apply in any way to the claims as currently pending.

C. *"Relative" Language Under M.P.E.P. 2173.05(b)*

The Examiner makes reference to M.P.E.P. 2173.05(b) apparently in reference to the usage of the term "substantially" in the claims. In this regard, it is first noted that the term "substantially" has been present in claims 1 and 58 for well over a year and no exception has been taken to this term in at least two previous reviews of the claims.

Second, the specification as originally filed is replete with a description of microhole sizes and porosity values across a stent body in accordance with the claimed invention as it relates to the term "substantially". See for example, the originally filed specification at page 11, lines 25-26; page 12, lines 12-13; page 15, lines 8-18; and, page 15, lines 24-26. Clearly this disclosure in the specification provides the requisite general guidelines necessary to ensure the definiteness of the claim. See, *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). Moreover, these portions of the specification also clearly lead one of ordinary skill in the art to know the scope of the claim, especially given the high level of skill (e.g., interventional cardiologists)

associated with those involved in this art. See, *Andrew Corp. v. Gabriel Electronics*, 847 F.2d 819, 6 USPQ2d 2010 (Fed. Cir. 1988).

## IV. Conclusion

In view of the foregoing, it is submitted that this response raises absolutely no new issues and, in fact, that all of these issues were affirmatively addressed in previous Amendments, including the identification of support under Section 112 for all claim recitations. As a result, all pending claims 1, 2, 30, 43-45, 58-64, 73 and 82-87 are now all in condition for allowance and this Response should be entered and the case allowed without further delay.

Respectfully submitted,

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